

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

EDWARD MCCALL,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 18-152V

Special Master Christian J. Moran

Filed: April 19, 2022

Entitlement; dismissal.

Andrew D. Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for petitioner;
Kyle E. Pozza, U.S. Dep't of Justice, Washington, DC, for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION¹

Edward McCall alleged that the Prevnar-13 and influenza (“flu”) vaccinations he received on January 18, 2017, caused him to develop rheumatoid arthritis. Pet., filed Jan. 31, 2018, at Preamble; ¶ 21. On March 30, 2022, Mr. McCall moved for a decision dismissing his petition.

I. Procedural History

Edward McCall filed a petition on January 31, 2018. After Mr. McCall filed his medical records, the Secretary filed his Rule 4(c) report on November 15, 2018, contesting entitlement. A status conference was then held on November 27, 2018, during which an onset dispute was identified. The parties agreed to move forward with expert reports. Instructions directed the experts to offer a medically

¹ The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

acceptable timeframe to infer causation. Order, issued Dec. 21, 2018, at 5-6. The experts were also instructed to explain when Mr. McCall's onset of symptoms began. Id. The parties were invited to comment on a draft version of the Instructions, issued on November 30, 2018, but did not object. Final Instructions were issued on December 21, 2018.

After several motions for extensions of time, Mr. McCall filed a revised expert report from Dr. Thomas Zizic on September 17, 2019. Exhibit 16.² In this report, Dr. Zizic asserted that after receiving the flu vaccine on January 18, 2017, Mr. McCall developed rheumatoid arthritis within approximately two months. See id. at 42. However, he also noted that Mr. McCall began complaining of joint pain and swelling by May 3, 2017. Id. at 33. Thus, Dr. Zizic acknowledges that Mr. McCall did not complain of joint pain or swelling until approximately 15 weeks post-vaccination. With respect to an appropriate temporal interval, Dr. Zizic stated that "eight weeks is on the outer edge of an appropriate onset interval, but still appropriate." Id. at 42. Dr. Zizic did not provide a basis for this opinion.

Dr. Zizic also maintained that "the vaccine triggered activation of B and/or T lymphocytes through molecular mimicry, cross-priming, immune complex formation or a combination of these." Id. at 42. He further asserted that the vaccine caused autoimmunity and triggered Mr. McCall's rheumatoid arthritis due to his genetic susceptibility. Id.

In response, the Secretary filed an expert report from Dr. Chester Oddis on January 29, 2020. Exhibit A. Dr. Oddis asserted that Dr. Zizic's theory on timing was "theoretical," and noted that Dr. Zizic did not offer medical literature supporting his proposed time interval. Id. at 6. He also opined that Dr. Zizic's causal theory was "largely hypothetical and could be applied to any external antigenic stimulus including unknown environmental agents or undiagnosed or clinically indolent infections." Id. He emphasized that experts in autoimmunity recommend patients with rheumatoid arthritis receive vaccinations. Id. at 5-6.

In a status conference held on March 2, 2020, the undersigned referenced his decision in Tullio v. Secretary of Health & Human Services, No. 15-51V, 2019 WL 7580149 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020), which found that the petitioner did not meet his burden under the

² Dr. Zizic's first attempt to express an opinion failed to comply with various aspects of the Instructions. Thus, his first report, filed on April 26, 2019, was struck and replaced with the revised report.

first Althen prong to show that the flu vaccine can cause rheumatoid arthritis. In a status report filed on April 1, 2020, Mr. McCall asserted that Tullio is distinguishable from his case, and expressed interest in filing an additional expert report from Dr. Zizic.

On July 31, 2020, Mr. McCall filed a supplemental expert report from Dr. Zizic. Exhibit 34. Dr. Zizic discussed the process of molecular mimicry generally, providing summaries of multiple scientific articles. Dr. Zizic did not discuss the onset of Mr. McCall's rheumatoid arthritis specifically in this report.

The Secretary filed a supplemental expert report from Dr. Oddis on March 10, 2021. Exhibit D. In this brief report, Dr. Oddis stated, "Dr. Zizic basically reviews the concept of molecular mimicry from an immunological perspective. He does not address the questions raised in my [report] and the bulk of his [report] is irrelevant to the case of Mr. McCall." Id. at 1. Dr. Oddis noted the limitations of exhibit 63 (Wang), a study Dr. Zizic relied on to show an increased risk of rheumatoid arthritis following the flu vaccine. Id. He stated that larger studies are needed to support a causal connection between rheumatoid arthritis and the flu vaccine. Id.

Along with Dr. Oddis's supplemental report, the Secretary filed expert reports from Dr. J. Lindsay Whitton and Dr. Lawrence Moulton. Exhibits E and H.

In Dr. Whitton's report, he asserted that Dr. Zizic's summary of Mr. McCall's medical history in his first report shows that Mr. McCall's onset occurred about 15 weeks following vaccination. Exhibit E at 4, citing exhibit 16 at 33-34. Dr. Whitton argued that this medical history was inconsistent with Dr. Zizic's assertion that Mr. McCall developed rheumatoid arthritis about two months after vaccination. Id. He added that Dr. Zizic did not provide any clarification on this point in his second expert report (exhibit 34). Id. Dr. Whitton asserted that if Mr. McCall's symptoms began on May 3, 2017, 15 weeks post-vaccination, the temporal relationship is not appropriate to infer causation. Id. at 5. He added that "a vaccine-induced adaptive immune response (primary or memory) begins to wane after ~3-4 weeks." Id.

Dr. Moulton agreed with Dr. Oddis and Dr. Whitton that Dr. Zizic's second report was "mainly composed of quotations from the biomedical literature purporting to support his theories regarding biological links between immunizations and [rheumatoid arthritis]." Exhibit H at 3. Dr. Moulton also disputed the reliability of some of the literature on which Dr. Zizic relied. Like Dr.

Oddis, Dr. Moulton noted methodological problems in the Wang article (exhibit 63). Id. at 4-9. Dr. Moulton concluded that there was no increased risk of rheumatoid arthritis following the flu vaccine. Id. at 9.

Mr. McCall filed a rebuttal expert report from Dr. Zizic on July 12, 2021. Exhibit 64. Dr. Zizic stated, “The best documentation of the onset of Mr. McCall’s [rheumatoid arthritis] in the contemporary medical records is from the office visit with Dr. Ritu Sadhu on May 16, 2017” Id. at 1. Dr. Zizic noted that during this visit, Mr. McCall reported “joint pains over the last several months.” Id., citing exhibit 3 at 27-30. Dr. Zizic asserted that this indicates onset of “at least two months” or “at least by March 16, 2017.” Id. at 2. Dr. Zizic therefore maintained that the onset of Mr. McCall’s rheumatoid arthritis occurred within two months after his vaccination. Id. He added that it is difficult for patients with rheumatoid arthritis to “pinpoint” the date of onset, especially if the patient suffers from other causes of joint disease, like Mr. McCall. Id.

The Secretary then filed supplemental reports from Dr. Oddis, Dr. Moulton, and Dr. Whitton on March 4, 2022. Exhibits J, K, and L.

In Dr. Oddis’s report, he reiterated that “there is no epidemiological evidence associating [the] influenza vaccination and [rheumatoid arthritis],” and that experts recommend vaccinations for patients with rheumatoid arthritis. Exhibit J at 1. With respect to onset, Dr. Oddis referenced five of Mr. McCall’s visits with Dr. Sadhu in the ten weeks following his flu vaccination, during which Mr. McCall only reported right shoulder pain, a preexisting condition. Id. at 2, citing exhibit 3 at 3, 6, 9, 12, 16, 23. Dr. Oddis emphasized that Mr. McCall did not report any other musculoskeletal complaints in the ten weeks following his vaccination, and only reported a change in symptoms at his visit on May 16, 2017. See id., citing exhibit 3 at 27. To Dr. Oddis, “it is difficult . . . to date the onset of [Mr. McCall’s rheumatoid arthritis]” because Mr. McCall did not report a change in his joint pain until May 16, 2017, despite several visits in the months prior. Id.

Dr. Whitton reiterated his belief that Dr. Zizic’s first report places Mr. McCall’s onset at 15 weeks post-vaccination. Exhibit K at 2, citing exhibit 16. He added that Dr. Zizic’s second report did not clarify questions regarding his assertion that Mr. McCall’s onset of rheumatoid arthritis occurred two months after vaccination. Id. Dr. Whitton opined that an appropriate time interval for onset of rheumatoid arthritis is six weeks and referenced the interval for Guillain-Barré syndrome following the flu vaccine as support. Id. Therefore, Dr. Whitton argued, both Dr. Zizic’s proposed interval of eight weeks and Mr. McCall’s likely onset of

symptoms 15 weeks post-vaccination far exceed the appropriate temporal interval. See id.

In Dr. Moulton’s supplemental report, he repeated his criticism of the studies and literature on which Dr. Zizic relied. See exhibit L. He reiterated that the epidemiological data does not support Dr. Zizic’s assertion that vaccines increase the risk of rheumatoid arthritis. Id. at 7. He added that the evidence does not support a finding that the flu vaccine, more likely than not, caused Mr. McCall’s rheumatoid arthritis. Id. at 7-8.

A status conference was held on March 21, 2022, during which the undersigned discussed the similarities between Mr. McCall’s case and Tullio in that in both cases, petitioners’ experts proposed similarities between the hemagglutinin portion of the flu vaccine and human collagen. The undersigned also indicated that Dr. Zizic did not answer the questions regarding timing in his last expert report. The undersigned raised concerns about the viability of Mr. McCall’s case and reasonable basis. Mr. McCall pointed out that some evidence differentiated Tullio from the present case, such as the participation of Dr. Zizic on behalf of Mr. McCall. In light of continued discussions, Mr. McCall requested 30 days to determine how to proceed.

On March 30, 2022, Mr. McCall moved to dismiss his case. Petitioner stated that “it has become clear to [him] that he will be unable to prove that he is entitled to compensation in the Vaccine Program.” Pet’r’s Mot., filed Mar. 30, 2022, at ¶ 1. Petitioner added that he intends to file a civil action. Id. at ¶ 5. The Secretary did not file a response to this motion. This matter is now ready for adjudication.

II. Analysis

To receive compensation under the National Vaccine Injury Compensation Program (hereinafter “the Program”), a petitioner must prove either 1) that the vaccinee suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations, or 2) that the vaccinee suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Under the Act, a petitioner may not be given a Program award based solely on the petitioner’s claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In this case, Mr. McCall filed medical records and expert reports in support of his claim, but nonetheless, wishes to have his claim dismissed and judgment entered against him. Though Mr. McCall filed this motion pursuant to 42 U.S.C. § 300aa-21(a) (regarding voluntary dismissal), the undersigned will construe this as a motion filed pursuant to 42 U.S.C. § 300aa-21(b) (regarding involuntary dismissal), given Mr. McCall's clear intent that a judgment issue in this case, protecting his right to file a civil action in the future. See Pet'r's Mot. at ¶ 5.

To conform to section 12(d)(3), a decision must "include findings of fact and conclusions of law." Here, although the parties could have submitted briefs, Mr. McCall conceded that "he will be unable to prove that he is entitled to compensation." Pet'r's Mot. at ¶ 1. Therefore, Mr. McCall has elected to seek a dismissal of his case. See Vaccine Rule 8(f).

In any event, the evidence weighs against a finding that the flu vaccine caused Mr. McCall's rheumatoid arthritis, given the finding in Tullio that the petitioner failed to establish that the flu vaccine can cause rheumatoid arthritis. See Tullio, 2019 WL 7580149, at *27. The finding in Tullio provides greater detail regarding the prong one aspect of this case—whether the flu vaccine can cause rheumatoid arthritis. Mr. Tullio presented opinions from two experts, Dr. Steinman and Dr. Utz, who are comparable to Dr. Zizic. After a robust development of whether molecular mimicry between hemagglutinin and collagen was a reliable theory, the undersigned found that Mr. Tullio had failed to meet his burden of proof. See id. at *12-22. This finding considered large epidemiologic studies that had failed to detect an increased incidence of rheumatoid arthritis among people receiving the flu vaccine.

Here, the evidence is similar. Importantly, the molecular composition of hemagglutinin has not changed, and the molecular composition of collagen has not changed. Although Mr. McCall and Dr. Zizic have been aware of the outcome of Tullio for approximately two years, they have not persuasively argued that any reliable evidence distinguishes Mr. McCall's case from Tullio. At best, Dr. Zizic may have raised some questions about one epidemiologic study, Ray (exhibit 62). See exhibit 34 at 21-22. The authors in Ray initially found an increased risk of rheumatoid arthritis following the flu vaccination in a cohort study but found no increased risk in an extended case control analysis. Exhibit 62 (Paula Ray et al., Risk of Rheumatoid Arthritis Following Vaccination with Tetanus, Influenza and Hepatitis B Vaccines Among Persons 15-59 Years of Age, 29 Vaccine 6592 (2011)). However, Dr. Zizic appears not to have any special training in biostatistics. See exhibit 15 (curriculum vitae). Therefore, on this point, the

opinion of Dr. Moulton, who has a Ph.D. in biostatistics, is more likely to be persuasive. Exhibit I (curriculum vitae).

While Mr. McCall's evidence regarding prong one falls short of the preponderance of the evidence standard, his case also suffers with respect to Althen prong three. In Dr. Zizic's opinion, the appropriate time for inferring that the flu vaccine caused rheumatoid arthritis is eight weeks. Exhibit 16 at 42. He did not provide support for this opinion. See id. Dr. Whitton disputed Dr. Zizic's assertion regarding an appropriate temporal interval. See exhibit K at 2 (opining that six weeks is an appropriate timeframe for onset of symptoms). As for the onset of Mr. McCall's rheumatoid arthritis, Dr. Zizic's opinion was deficient. Dr. Zizic claimed that Mr. McCall's onset of rheumatoid arthritis occurred within two months following vaccination. Exhibit 16 at 42. However, the Secretary's experts persuasively argued that there is insufficient evidence to place Mr. McCall's onset at two months post-vaccination. See exhibit A (Dr. Oddis's first report) at 2; exhibit K (Dr. Whitton's supplemental report) at 2.

At the end of the day, despite able advocacy from Mr. Downing, Mr. McCall did not proffer evidence of sufficient quality or quantity that would suggest that the flu vaccine caused his rheumatoid arthritis. Thus, Mr. McCall's choice to seek dismissal voluntarily seems to be an appropriate conservation of resources.

Thus, the Motion for Decision is GRANTED and this case is DISMISSED WITH PREJUDICE for insufficient proof. The Clerk shall enter judgment accordingly. See Vaccine Rule 21(b).

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master